K073030

510(k) Summary

JUL 21 2008

Identification of the submitter:

Submitter:	Andon Health Co., LTD No 31, Changjiang Road, Nankai District, Tianjin, P.R. China, 300193
Telephone number:	86-22-6052 6161
Fax number:	86-22-6052 6162
Contact:	Liu Yi
Date of Application:	08/10/07

Identification of the product:

Trade name:	AG-605 Blood Glucose Monitoring System AG-606 Blood Glucose Monitoring System
Common name:	Glucose test System
Classification:	Blood Glucose Meter and test strip are Class II devices (21 CFR 862.1345, Glucose Monitor)
Product code:	CGA

Predicate Device:

One Touch Ultra Blood Glucose Monitoring system of Life Scan

510k number: K024194

Device description:

AG-605 & AG-606 Blood Glucose Monitoring System consists of a blood glucose meter, test strips, two levels of control solutions, lancets and lancing device.

AG-605 & AG-606 Blood Glucose Monitoring System is designed to provide an easy, accurate method for determining capillary blood glucose values. This analysis is based on amperometric technology using glucose oxidase that is specific for the blood glucose measurement. When the blood sample is applied to the test strip, electrons are formed by the reaction between glucose oxidase and blood glucose. The electrical current is measured by the meter and correlates with the concentration of glucose in the blood sample.

Intended use:

AG-605 & AG-606 Blood Glucose Monitoring System is intended for in vitro diagnostic use. The system is intended to be used for the quantitative measurement of capillary whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Comparison to Predicate Devices(s):

CHARACTERISTICS	NEW DEVICE: AG-605 & AG-606 Blood Glucose Monitoring System	PREDICATE: One Touch Ultra Blood Glucose Monitoring system (K024194)
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	30-55%	30-55%
Operating Temperature Range	10℃~40℃(50°-104°F)	6℃~44℃(43°-111°F)
Dimensions	AG-605: 50mmx 112mmx 22mm AG-606: 82 mm×59mm×20mm	3.12″ X2.25″ X0.85″
Weight	AG-605: 60g (exclude batteries) AG-606: 55g (exclude batteries)	1.5 ounces (43g) with battery
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	AG-605: 160 times with time and date displaying AG-606: 350 times with time and date displaying	150 blood glucose and control solution tests
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC3V (2XAAA batteries)	One replaceable 3.0v lithium battery
Battery Life	Approx. 1000 normal tests	1000 tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-600 Test Strip	ONETOUCH Ultra Test Strip
Sample Volume	Minimum 1 micro liter	Minimum 1 micro liter

Summary:

The information provided in this pre-market notification demonstrates that AG-605 & AG-606 Blood Glucose Monitoring System is substantially equivalent to One Touch Ultra Blood Glucose Monitoring system. Substantial equivalent was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the AG-605 &AG-606 Blood Glucose Monitoring System is safe and effective for its stated intended use.

Clinical Tests:

Clinical tests were performed and complied the accuracy requirements of ISO 15197. The results meet or exceed the accuracy requirements of ISO 15197.

Non-clinical Tests:

All non-clinical tests coincide the following standards, including Product Safety test and Electromagnetic Compatibility test.

IEC 61010-1-2001

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

IEC 61010-2-101-2002

Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61326

Electrical equipment for measurement, control and laboratory use —— EMC requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Andon Health Co., Ltd.
c/o Ms. Mona
Technologl Department
7th Floor Hua Qiao Chuang Ye Plaza
No. 10 JinPing Road, Ya An Road
Nankai District, Tianjin, P.R. China 300193

JUL 21 2008

Re: k073030
Trade Name: AG-605 Blood Glucose Monitoring System, AG-606 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: July 9, 2008
Received: July 14, 2008

Dear Mona:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073030

Device Name: AG-605 Blood Glucose Monitoring System
AG-606 Blood Glucose Monitoring System

Indication For Use:

AG-605 & AG-606 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. Testing is done outside the body (In Vitro diagnostic use). It is indicated for both lay uses by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus. Not for use on neonates.

Prescription Use _____ And/Or Over the Counter Use Yes
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Jean Cooper

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073036